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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,770	11/19/2001	Steven Leigh	2001-1087A	7884

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,770

Applicant(s)

Leigh

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 11, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-22 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The request for the extension of time and amendment filed on 7-11-03 are acknowledged.

Claims included in the prosecution are 12-22.

Claim Rejections - 35 USC § 112

1. **The following is a quotation of the first paragraph of 35 U.S.C. 112:**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Claims 12-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The negative limitation 'that the carboxylic acid is not retinoic acid' now introduced in claims 12 and 19-22 has no support in the specification as originally filed and therefore, deemed to be new matter.**

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Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 12-13 and 19-22 are rejected under 35 U.S.C. 102(a) as being anticipated by Mehta (5,811,119)..

Mehta discloses powders containing phospholipids and retinoic acid. The powder upon reconstitution forms liposomes (note the abstract and examples, example 1 in particular).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 12-15 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Roux (6,103,259) or Hayward (5,585,109) in combination with Mehta cited above.

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Roux discloses liposomal preparations containing alpha hydroxy acids such as salicylic acid (note the abstract, col. 2, line 54 through col. 5, line 3). Roux however, does not teach the preparation of liposomes in the form of a powder.

Hayward similarly discloses liposomal compositions containing salicylic acid (note the abstract, and examples). Hayward however, does not teach the preparation of liposomes in the form of a powder.

Mehta as discussed above, teaches that the liposomes can be prepared in a powdery form and when needed an aqueous medium is added to the powders to form liposomes.

It would have been obvious to one of ordinary skill in the art to lyophilize the liposomal compositions in the form of powders and reconstitute liposomes upon addition of an aqueous medium just before use since such a method is routinely and conveniently practiced in the art as shown by Mehta.

Applicants' arguments have been fully considered, but are not found to be persuasive. Applicants argue that Mehta is concerned with the specific use of retinoic acid and an intercalation promoter for the intravenous treatment of cancer and that there is no teaching that the composition could be used topically. These arguments are not found to be persuasive since the secondary reference of Mehta is combined for its teachings of the powdery preparations of liposomes which could be converted into liposomes when needed and this will be the same irrespective of the purpose for which the liposomes are used.

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Applicants' arguments with regard to Roux, and Hayward pertain to the method of preparation; according to applicants Roux's process requires a surfactant and that of Hayward requires a water-soluble organic base. These arguments are not found to be persuasive. First of all, claims 12-18 are composition claims and not method claims; the instant claim language either in the composition claims or method claims does not exclude the presence or use of surfactant in Roux or organic base in Hayward.

7. Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Roux (6,103,259) or Hayward (5,585,109) in combination with Mehta cited above, further in view of either Touitou (5,716,638) or Ribier (5,614,215).

What is lacking in Roux, and Hayward is the inclusion of a xanthine such as caffeine.

Touitou while disclosing phospholipid containing compositions for application to the skin teaches the use of a combination of caffeine and salicylate (note the abstract and Example XVII on col. 10).

Ribier while disclosing liposomal compositions for application to the skin teaches that a combination of a keratolytic agent such as salicylic acid along with a liporegulating agent such as caffeine could be used (note the abstract, col. 6, lines 56-60).

The inclusion of caffeine in the compositions containing a salicylic acid of Roux or Hayward would have been obvious to one of ordinary skill in the art since the references of Touitou, and Hayward show the routine practice in the art of using a combination of

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salicylate and a Xanthine such as caffeine; one of ordinary skill in the art would expect the benefits of both agents from the resulting combination.

Applicants' arguments have been fully considered, but are not found to be persuasive. Applicants' arguments with regard to Roux, Hayward and Mehta have been addressed above. Applicants while agreeing that Touitou's compositions are topical argue that those compositions require the presence of aliphatic alcohol whereas instant compositions do not contain an alcohol component. Similarly, applicants argue that Ribier requires the presence of two components. These arguments are not found to be persuasive since these references are combined for their teachings of caffeine; furthermore, as pointed out above, instant claim language does not exclude the additional components in Touitou or Ribier.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

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All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

September 23, 2003